effectiveness of overall hygiene methods to control dental plaque accumulation. Subgingival calculus interferes with the regeneration of lost periodontal attachment.

The removal of calculus is considered a basic step in the prevention and treatment of inflammatory periodontal diseases. The formation of supragingival calculus can be limited through mechanical or chemical methods. Preventing subgingival calculus formation, if possible, would not necessarily reduce gingivitis, because a surface currently free of calculus can still harbor plaque. Present methods do not allow for the predictable prevention of subgingival calculus.

4. Gingivitis

Gingivitis, an inflammation of the gingiva, affects most of the population at one time or another. The signs of gingivitis are tissue swelling and redness, loss of stippling, glossy surface, and increased tissue temperature. The gingiva may also bleed upon gentle provocation, such as toothbrushing, or may bleed spontaneously. Some signs of gingivitis, such as bleeding, can be identified by lay persons.

Gingivitis is a response to injury, often resulting in localization of tissue damage and neutralization of the effects of injurious agents. If the injurious agents cannot be adequately neutralized or eliminated, they may lead to chronic inflammation of the soft tissue and periodontitis. While most cases of periodontitis are believed to start with gingivitis, most cases of gingivitis do not progress to periodontitis. Histologically, gingivitis is characterized by inflammatory exudate or infiltrate, loss of collagen of the gingival connective tissue, and proliferation of the epithelium into the infiltrated tissue. Sometimes the epithelium lining the sulcus (crevice bounded by the tooth and free gingiva) may develop microulcerations. In gingivitis, the junctional epithelium usually is at or near the cementoenamel junction (junction of the tooth crown and root).

Gingivitis, especially when severe, may be self-diagnosable because people can recognize some of the signs of gingivitis, such as bleeding, gingival discoloration, and swelling, which gives rise to pseudopockets (pocket-like structure caused by inflammation of the gingiva without effecting the sulcus base). In the early stages of gingivitis when there is little or no pseudopocket formation, only noncalcified plaque, and little or no calculus, thorough daily oral hygiene may resolve the disease. Under these conditions, self-treatment of gingivitis is appropriate. When OTC drug products for the prevention and control of plaque-associated gingivitis are used as part of a program of good oral hygiene, including regular dental checkups, they can help consumers maintain their gingival health.

The most common form of gingivitis is termed marginal gingivitis and occurs in all individuals at some time. It is limited to the gingivae around the collar of the tooth. However, people are seldom easily able to detect sites with mild gingivitis because there may be no pain or bleeding. Plaque-associated gingivitis, an inflammation of the interdental and marginal gingiva, can be controlled or prevented by removal or inhibition of microbial plaque accumulation. Chemotherapeutic agents can enhance the benefits of traditional methods of oral cleansing by toothbrushing with a dentifrice and regular use of dental floss and other cleaning aids.

Readily available OTC drug products for the prevention and control of plaque-associated gingivitis are intended to play a significant public health role. However, the effects of these products in periodontitis have not been determined in large scale studies. OTC drug products are useful adjuncts to, but do not replace, regular professional care.

In the later stages of gingivitis with the formation of pseudopockets and calculus, it becomes more difficult for people to resolve the gingivitis. Therefore, self-treatment has limited potential for resolution of severe gingivitis, which should be treated as part of a regular professional care program. Gingivitis can progressively worsen and lead to the development of pockets that can be difficult for people to clean.

5. The Interrelationship Between Plaque and Gingivitis

Dental plaque can be causally related to gingivitis. A critical plaque mass at the gingival margin for a particular length of time can initiate change. However, the Subcommittee has no knowledge of any studies where the volume, mass, or amount of plaque can be closely equated with the extent of gingival inflammation. There is a general, positive relationship between supragingival plaque levels and levels of gingivitis. For example, with little or no supragingival plaque accumulation, most often there is gingival health, whereas heavy levels of plaque accumulation, especially at the gingival margin, are often associated with gingivitis.

Plaque forms readily on tooth surfaces in individuals with poor oral hygiene. It takes, histologically, about 3 to 4 days with no oral hygiene in periodontally healthy subjects to develop microscopic evidence of gingivitis. This evidence consists of infiltration of the gingival epithelium, especially the junctional epithelium, with inflammatory cells (including neutrophils), infiltration of the gingival connective tissue with lymphocytes, and beginning loss of collagen.

The Subcommittee does not know how long plaque must be present before gingivitis spontaneously appears. When distinguishing between experimentally induced gingivitis and spontaneous gingivitis (developing under conditions of normal oral hygiene) the following are found: (1) Most subjects over a period of 1 to 3 weeks of cessation of oral hygiene developed gingivitis measurable with clinical indices, and (2) subjects must accumulate a certain level of plaque before clinical signs of gingivitis are apparent. In addition, mature plaque with complex flora appears to be correlated with gingivitis. However, mature plaque, comprised of a complex gram-positive and gram-negative flora with motile organisms, is often associated with spontaneous gingivitis.

The Subcommittee accepts that gingivitis is associated with an accumulation of plaque along the gingival margin but is unaware of any evidence that shows that there is a close correlation between the amount of plaque and the induction of gingivitis, as can be assessed using present day methods. It should be noted that the relationship between the quantity of plaque present and the degree of gingivitis is sufficiently complex such that reductions in plaque mass alone are inadequate to conclude that a therapeutic effect on gingivitis could be expected. Therefore, gingivitis reductions must be measured directly.

6. Periodontitis

Most cases of periodontitis are believed to start with gingivitis, although not all cases of gingivitis lead to periodontitis. Periodontitis is characterized clinically by gingivitis of varying severity, loss of periodontal attachment, increased probing depth, and radiographically detectable loss of alveolar and supporting bone. In advanced disease, the teeth may become increasingly mobile. Progression of gingivitis and the relationship of gingivitis to the onset of periodontitis are not well understood. However, one approach to addressing this relationship comes from human studies in which meticulous oral hygiene leading to excellent plaque control and control of gingivitis appears to prevent the onset of